

REMARKS

Upon entry of the foregoing amendments to the claims, claims 12-19 and 21-33 will be pending. Among them, claims 21-33 are under examination. Applicant has canceled previously-presented claims 1-11, and 20, amended claims 21 and 22, and added new claims 24-33. Claims 12-19 were previously withdrawn for covering a non-elected invention. No new matter has been introduced by the foregoing amendments.

The Applicant notes that the Examiner checked the boxes in paragraph (10) of the Office Action Summary but provided no further explanation as to the drawing objections:

Application Papers

- 9) ☐ The specification is objected to by the Examiner
10) ☒ The drawing(s) filed on 11 March 2005 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152

The Applicant respectfully requests clarification of the objections to the drawings, if any, in the next office communication.

Claims 21-23

Previously-presented claims 21-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stewart et al. (US 5128048) in view of Nishimura (EP 0591980 A2).

Based on the comments provided by the Examiner on pages 5-7 of the final office action dated September 29, 2010, the Examiner appears to read the elements of Stewart and Nishimura as corresponding to the elements of previously-presented claim 21 as follows:

Claim 21	Stewart and Nishimura
Collecting container	Primary bag 16 (Stewart)
First satellite container	Transfer container 32 (Stewart)
Second satellite container	Transfer container 28 (Stewart)
Leukocyte filter	Separation device 36 (Stewart) implemented as a leukocyte filter (Nishimura)

Applicants would like to address the deficiencies of the combination of Stewart and Nishimura in the context of amended claim 21 based on the correspondence of elements set forth in the table above.

Amended claim 21 is directed to a device for separating blood into blood components, such device including (amended version?):

- a collecting container that receives whole blood;
- a leukocyte filter that filters the whole blood so as to remove leukocytes from the whole blood and allow platelets to pass through the filter;
- a first satellite container physically coupled to the collecting container by a first conduit that includes the leukocyte filter;
- a second satellite container physically coupled to the collecting container by a second conduit that includes the leukocyte filter and a third conduit that bypasses the leukocyte filter;
- a plurality of valves selectively operable to control fluid flow between the containers including:
 - controlling fluid flow from the collecting container to the first satellite container via the first conduit that includes the leukocyte filter,
 - controlling fluid flow from the collecting container to the second satellite container via the second conduit that includes the leukocyte filter,
 - controlling fluid flow from the second satellite container to the collecting container via the third conduit that bypasses the leukocyte filter.

Even if the separation device 36 of Stewart's blood collecting system is replaced with the leukocyte filter of Nishimura as suggested by the Examiner, the resultant system does not "[control] fluid flow from the collecting container to the first satellite container via the first conduit that includes the leukocyte filter," as required in currently amended claim 21.

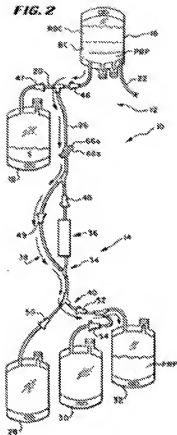
Applicant observes that Stewart's blood collecting system requires three distinct transfer paths: (1) a first transfer path 34 that leads from the primary bag 16 of the blood collection assembly 12 to the transfer container 28 of the transfer assembly 14 through the separation device 36 (see, FIG. 3, col. 5, lines 15-18, col. 6, lines 19-25); (2) a second transfer path 38 that leads from the primary bag 16 to the transfer container 32 bypassing the separation device 36 (see, FIG. 2, col. 5, lines 39-42, col. 6, lines 14-19); and (3) a

third transfer path 40 that leads from the transfer container 28 to the satellite bag 18 bypassing the separation device 36 (see FIG. 4, col. 5, lines 43-46, col. 6, lines 27-32).

Based on the correspondence of elements set forth in the table above, the only transfer path of Stewart that can reasonably be read as **"controlling fluid flow from the second satellite container to the collecting container via the third conduit that bypasses the leukocyte filter"** is Stewart's "third transfer path 40" (depicted in FIG. 4 of Stewart), and the only transfer path of Stewart that can reasonably be read as **"controlling fluid flow from the collecting container to the second satellite container via the second conduit that includes the leukocyte filter"** is Stewart's "first transfer path 34" (depicted in FIG. 3 of Stewart).

According to FIG. 2 of Stewart, the only remaining transfer path described in Stewart is the "second transfer path 38", which leads from the primary bag 16 to the transfer container 32 thus completely bypassing the separation device 36:

FIG. 2



As can clearly be seen, even if Stewart's "primary bag 16" is read as corresponding to the claimed "collecting container," Stewart's "transfer container 32" is read as corresponding to the claimed "first satellite container," and Stewart's separation device 36 is implemented as a leukocyte filter, Stewart's "second transfer path 38" does not allow fluids to flow from the primary bag 16 to the first satellite container via a conduit that includes the separation device 36. Rather, Stewart's "second transfer path 38" causes fluids to bypass the separation device 36 altogether.

Moreover, the device that results from combining Stewart and Nishimura in the manner suggested by the Examiner does not disclose the claimed "plurality of valves selectively operable to control fluid flow between the containers including: controlling fluid flow from the collecting container to the first satellite container via the first conduit that includes the leukocyte filter," as required in amended claim 21.

For at least these reasons, claim 21 is allowable over the combination of Stewart and Nishimura.

Dependent claims 22 and 23, which incorporate all of the features of claim 21, are allowable over the combination of Stewart and Nishimura for at least the same reasons given above with respect to claim 21.

New claims 24-33

New claim 24 is directed to a blood separation system that includes:

- a primary receptacle for containing platelet rich plasma (PRP) and packed red cells (PRC);
- a leukocyte filter for filtering leukocytes and allowing platelets to pass through;
- a first secondary receptacle for receiving leukocyte depleted PRP from the primary receptacle;
- a second secondary receptacle for receiving leukocyte depleted PRC from the primary receptacle; and
- a set of flow controllers selectively operable to provide:
 - a first fluid pathway, wherein fluids flow from the primary receptacle to the first secondary receptacle through the leukocyte filter,
 - a second fluid pathway, wherein fluids flow from the primary receptacle to the second secondary receptacle through the leukocyte filter, and
 - a third fluid pathway, wherein fluids flow from the second secondary receptacle to the primary receptacle without passing through the leukocyte filter.

The combination of Stewart (US 5128048) and Nishimura (EP 0591980 A2) does not disclose all of the features of new claim 24, in particular, the claimed "first fluid pathway, wherein fluids flow from the primary receptacle to the first secondary receptacle through the leukocyte filter."

New claim 24 requires, in part, "a third fluid pathway, wherein fluids flow from the second secondary receptacle to the primary receptacle without passing through the leukocyte filter." The only transfer path of Stewart that can reasonably be read as corresponding to the "third fluid pathway" is Stewart's "third transfer path 40" (depicted in FIG. 4 of Stewart), which leads from the transfer container 28 to the primary bag 16

bypassing the separation device 36. This requires that the skilled person read Stewart's "primary bag 16" as corresponding to the "primary receptacle" of claim 24 and Stewart's "transfer container 28" as corresponding to the "second secondary receptacle" of claim 24.

If Stewart's "primary bag 16" is read as corresponding to the "primary receptacle" of claim 24 and Stewart's "transfer container 28" is read as corresponding to the "second secondary receptacle" of claim 24, the only transfer path of the two remaining transfer paths described in Stewart that provides for fluids to flow from the primary receptacle to the second secondary receptacle through the leukocyte filter is Stewart's "first transfer path 34" (depicted in FIG. 3 of Stewart), which leads from the primary bag 16 of the blood collection assembly 12 to the transfer container 28 of the transfer assembly 14 through the separation device 36.

Claim 24 requires a "first fluid pathway, wherein fluids flow from the primary receptacle to the first secondary receptacle through the leukocyte filter." The only remaining transfer path described in Stewart cannot be read as corresponding to the claimed "first fluid pathway" because Stewart's "second transfer path 38" (depicted in FIG. 2 of Stewart) leads from the primary bag 16 to the transfer container 32 bypassing the separation device 36.

The combination of Stewart and Nishimura does not disclose a blood separation system that includes a set of flow controllers selectively operable to provide "a first fluid pathway, wherein fluids flow from the primary receptacle to the first secondary receptacle through the leukocyte filter" as required in new claim 24. For at least this reason, the Applicant respectfully submits that new claim 24 and its dependent claims are allowable over the combination of Stewart and Nishimura.

New claim 33 is directed to a method for separating blood into leukocyte depleted blood components that includes:

- providing a blood separator device comprising the device of claim 21;
- separating blood collected in the collecting container into a platelet rich plasma (PRP) blood component and a packed red cell (PRC) blood component;

feeding the PRP from the collecting container into the first satellite container through said leukocyte filter to provide a leukocyte depleted first blood component into said first satellite container, wherein PRC remains in the collecting container;
adding into the collecting container an additive solution for the PRC; and
feeding said PRC suspended in the additive solution into the second satellite container passing through said leukocyte filter.

New claim 33, which incorporates all of the features of claim 21, is allowable over the combination of Stewart and Nishimura for at least the same reasons given above with respect to claim 21. Stewart and Nishimura, alone or in combination, do not disclose the method for separating blood into leukocyte depleted blood components as recited in new claim 33.

Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The excess claims fee in the amount of \$52 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 7B901-004US1.

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